K010711

MAY 22 2001

510(k) Summary
Advanced Surgical Concepts
Ecotract Adjustable Wound Protector/Retractor

1. SPONSOR

Advanced Surgical Concepts (ASC)
Unit 4, Sunnybank Centre
Bray, Co. Wicklow
Ireland

Contact Person: Tanya Hoolahan
Telephone: 353 1 2864777

Date Prepared: March 8, 2001

2. DEVICE NAME

Proprietary Name: Ecotract Adjustable Wound Protector/Retractor
Common/Usual Name: Drape and Retractor
Classification Name: Surgical drape or surgical retractor

3. PREDICATE DEVICES

- 3M Steri-Tractor Wound Retractor K870543
- Medical Creative Technologies Protector Retractor K954824

4. DEVICE DESCRIPTION

The Ecotract Adjustable Wound Protector/Retractor consists of four rings joined by an impermeable retraction sleeve that opens the incision. The design of the Ecotract allows visibility of the wound while protecting the edges of the incision. The retraction is applied through the locking of a flexible ring to a rigid upper ring. The ASC Ecotract Adjustable Wound/Protector Retractor is provided in four aperture sizes.

During use, the abdominal wall is incised and the distal ring is placed through the incision ensuring that no viscera are trapped between the distal ring and the abdominal wall. The device is secured in place with the proximal rings on the

abdominal surface by pulling the sleeve material through the proximal rings using the stop-ring as a grip. When the incision has been adequately retracted on one side, the sleeve is stretched over the retaining tabs on the outer proximal ring. This action secures the device. This is repeated on the other side until both sides of the incision are adequately retracted.

5. INTENDED USE

The Ecotract Adjustable Wound Protector/Retractor is intended to provide exposure in abdominal surgery, isolate the surgical incision, and protect the wound from contamination

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The determination of substantial equivalence of the Ecotract Adjustable Wound Protector/Retractor and cited predicates is based on similarities in intended use, technology, and operational characteristics.

The technological characteristics and the basic design of the Ecotract Adjustable Wound Retractor/Protector are similar to the substantially equivalent devices. All of the devices provide access to the abdominal area while protecting the incision edges.

The Ecotract Adjustable Wound Retractor/Protector and Steri-Tractor both use rings for positioning. The Ecotract Adjustable Wound Retractor/Protector uses four rings. The MCT Protector Retractor uses two rings and the Steri-Tractor uses a single ring. The Ecotract Adjustable Wound Retractor/Protector and MCT Protector Retractor use the rings to hold the incision open.

7. PERFORMANCE TESTING

Testing demonstrated that materials used in the manufacture of the ASC Ecotract Adjustable Wound Protector/Retractor are biocompatible and the device fulfills performance specifications. Additionally, performance testing showed that the Ecotract protects the wound, secures the device in the incision, and retains constant retraction over time. The testing also showed that the Ecotract can be used in various abdominal thicknesses and has retraction and wound protection capabilities comparable to the MCT device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2001

Advanced Surgical Concepts (ASC)
Ms. Mary McNamara-Cullinane
Staff Consultant
C/o Medical Device Consultants, Inc
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K010711
Trade Name: Ecotract Adjustable Wound Protector/Retractor
Regulation Number: 876.1500 and 878.4370
Regulatory Class: II
Product Code: GCJ and KKX
Dated: March 8, 2001
Received: March 9, 2001

Dear Ms. McNamara-Cullinane:

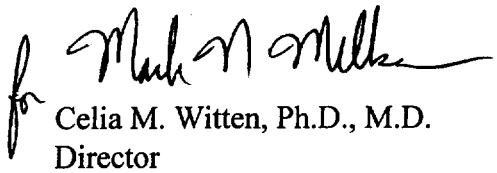
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010711

Device Name:

Advanced Surgical Concepts Ecotract Adjustable Wound Protector/Retractor

Indications for Use:

The Ecotract Adjustable Wound Protector/Retractor is intended to provide exposure in abdominal surgery, to isolate the surgical incision and to provide protection against wound contamination.

(Please Do Not Write Below This Line - Continue On Another Page If Necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010711

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)